

SUPPLEMENTARY INFORMATION
CERTIFICATE OF A PHARMACEUTICAL PRODUCT

1. Requester information (provide name; firm; address; telephone number; FAX number; firm Tax ID code):

2. Section 1.0, provide proprietary name and dosage form:

3. Section 1.1, provide active ingredient and amount per unit dose. Note: This information may be provided in the approved product labeling and may be attached to the certificate. For certificate requests for more than one country, provide a copy of the attachments for each country. Provide one copy of the attachments for FDA. Attachments are limited to a total of 10 pages:

4. Section 2A.1 & 2A.2, provide Product license holder name, address and U.S. license number; product license number and date of issue (provide a copy of the approval letter as verification of the product license or NDA number and approval date):

5. Section 2A.3 or 2B.2, Indicate status of Product license holder: a=manufacturer; b=packager and/or relabeler, or c=neither

6. List all facilities involved in the manufacturing of the exported product (Name; Address; license number, if applicable; registration number; date of most recent inspection):

7. Section 2A.3.1, Do you want the manufacturing location(s) listed on the certificate?

8. Importing Country(ies):

9. Number of certificates requested:

10. For unapproved biological drugs, section 2B.3, indicate the appropriate category for why authorization is lacking: not required/not requested/under consideration/refused

EXPORTER'S CERTIFICATION STATEMENT - "Certificate of a Pharmaceutical Product"

Firm Name:

As the responsible official or designee of the company named above, I hereby certify to the United States Food and Drug Administration that:

- the company, the manufacturing plant, and the product being exported, as identified in the Supplementary Information, continue to be, to the best of my knowledge, in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act;
- the product being exported has been manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements; and
- the product labeling provided with the Supplementary Information is a true and accurate representation of the product labeling approved by the FDA.

Signature

Date

Name and Title

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.